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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/071,400 | 02/07/2002 | Ni Ding | 10177-111-999 | 1077 |

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| EXAMINER | |
|---|---|
| THOMPSON, MICHAEL M | |
| **ART UNIT** | **PAPER NUMBER** |
| 3763 | |

DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/071,400 | DING ET AL. | |
| | Examiner | Art Unit | |
| | Michael M. Thompson | 3763 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *18 June 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *14-33 and 47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-33 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 May 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the perfusion lumen of claim 18 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. The proposed drawing correction has not been entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### *Specification*

2. The amendment filed 05/06/2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: All references to Figure 2c and any reference numbers not originally presented. It appears that the specification is not sufficiently descriptive to provide any potential depiction. Drawing 2c constitutes new subject matter since it is unclear what Applicant originally envisioned as the configuration for the infusion lumen that supplies the sponge coating.

Applicant is required to cancel the new matter in the reply to this Office Action.

*Claim Rejections - 35 U.S.C. § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 14, 17-23, 25, 27-33, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Racchini et al. (5,458,568) in view of Sahatjian (5,304,121). Racchini et al teaches all of the limitations of the claims except for explicitly reciting a non-hydrogel polymer having a plurality of voids. Sahatjian teaches the use of a non-hydrogel polymer having a plurality of voids. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the sponge coating of Racchini et al. with the non-hydrogel polymer

sponge coating of Sahatjian for the well known purpose of releasing drug solutions to a patient due to the compressibility of sponge-like polymers in response to pressure.

6. Claims 14-33 and 47 rejected under 35 U.S.C. 103(a) as being obvious over Racchini et al. in view of Ding et al. (U.S. No's 6,099,562; 6,284,305; 6,620,194)

The applied references has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2). Racchini et al teaches his drug delivery balloon for use with several anticipated post treatments such as coatings to include all of the limitations of the claims except for explicitly reciting a biostable sponge coating comprising a non-hydrogel polymer having a

plurality of voids. Ding et al. collectively teach the use of a biostable sponge coatings that comprise non-hydrogel polymers having a plurality of voids by several methods. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the device of Racchini et al. with the non-hydrogel polymer sponge coating of Ding et al. for the well known purpose of releasing drug solutions to a patient due to the compressibility of sponge-like polymers in response to pressure. It should be noted that Ding et al. further states that the topcoat may cover between 10% to 95% of the surface when applied to create the voids or breaks thereby satisfying void space requirements.

7. Claims 15-16, 24, 26, 33, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Racchini et al. (5,458,568) in view of Sahatjian (5,304,121) as applied to claims 14, 17-23, 25, and 27-33 above, and further in view of Helmus et al. (5,447,724). Racchini et al. and Sahatjian teach all of the limitations of the claims except for explicitly reciting voids with space of the coating greater than about 60% of the volume of the coating wherein the particulate material is eluted *in vivo* with or without a solvent. Helmus et al. teaches a coating or reservoir that contains a particulate material or agent comprising more than about 30% by weight of the agent to the reservoir, preferably about 40% to 60% by weight of the agent which is eluted *in vivo*. Therefore, Helmus et al. is specifically teaching voids large enough to carry within the reservoir comprised "voids" capable of containing particulate or agent in the percentages supra. It is well known that "voids" or "pore" in the reservoir of coatings are commonly constructed via elution or extraction of particulate matter and the porosity is determined by the size of the elutable particles ...and by the concentration of those particles as a percent by volume of a pre-elution mixture thereof with the polymer. This is consistent with the

teachings of Helmus et al. with respect to coatings. It is submitted, therefore, that it would have been obvious to one of ordinary skill in the art, at the time of invention, to have modified the sponge coating of Sahatjian with the characteristics supra of Helmus et al. for the well known purpose of a prolonged release at effective levels for several hours and/or for the purpose of releasing a greater quantity of agent to the patient.

***Double Patenting***

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 13-33 and 47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 6,099,562 in combination with Racchini et al. (5,458,568). Similarly, Racchini et al teaches his drug delivery balloon for use with several anticipated post treatments such as coatings to include all of the limitations of the claims except for explicitly reciting a biostable sponge coating comprising a non-hydrogel polymer having a plurality of voids. Ding et al. collectively teach the use of a biostable sponge coatings that comprise non-hydrogel polymers having a plurality of voids by several methods. It would have been obvious to one of ordinary skill in the art, at the time of

invention to have modified the device of Racchini et al. with the non-hydrogel polymer sponge coating of Ding et al. for the well known purpose of releasing drug solutions to a patient due to the compressibility of sponge-like polymers in response to pressure. It should be noted that Ding et al. further states that the topcoat may cover between 10% to 95% of the surface when applied to create the voids or breaks thereby satisfying void space requirements.

### *Response to Arguments*

10. Applicant's arguments with respect to claims 14-33 and 47 have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment.

### *Conclusion*

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

**Contacts**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for all submissions to the organization where this application or proceeding is assigned is (703) 872-9306.

Michael M. Thompson

Patent Examiner

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MT

August 16, 2004